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BENNETT EXAMINER

F3M1/0131

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ART UNIT	PAPER NUMBER
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3307

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DATE MAILED: 01/31/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-24 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1835 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the application serial number(s) of the application(s) upon which applicant is claiming benefit under 35 U.S.C. 120.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the claimed invention.

With respect to the recitation of claim 3, no specific distances have been disclosed for the outwardly projecting edges, nor any minimum distance which would enable the edges to embed in the vascular wall.

With respect to claims 5-7, although the cylindrical elements are disclosed as having U-, Y-, and W-shaped members, it is not apparent what applicant considers the connecting elements if the cylindrical elements included such shaped members because it appears that the Y-, and W-shaped members are nothing more than part of the normal serpentine pattern and

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further including the connecting element attached thereto (particularly, the Y-shaped members).

Claims 3 and 5-7 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim 3 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 3, it is not apparent specifically what distance is being referred to by the phrase "a distance... sufficient enough to embed in the vascular wall", nor what distance would be sufficient. Further, it does not appear that this recitation clearly defines a single distance, as it appears that, depending upon a number of factors, such as the diameter of the vessel, the thickness of the wall, etc., different distances could apply.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for

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patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4, and 8-22 are rejected under 35 U.S.C. § 102(e) as being anticipated by Palmaz ('417).

Palmaz teaches a stent 70 comprising: a plurality of cylindrical elements 71; a plurality of parallel connecting elements 100, see fig. 7; said stent having an outer wall which, as seen in fig. 10, has a plurality of outwardly projecting edges when said stent is in a fully expanded condition; said stent is smooth when in a non-expanded condition; said cylindrical elements 71 having a plurality of peaks and valleys having a serpentine pattern; said stent can be made of stainless steel or tantalum and is formed of a single piece and made of the same material; the connecting elements 100 consist of up to four and are uniformly circumferentially displaced with respect to the longitudinal axis of the stent; in an expanded condition, each cylindrical element has a length less than its diameter, as seen in fig. 10; said stent can be expanded a small distance radially outwardly without appreciably shortening. It would appear that the outwardly projecting edges of Palmaz as seen in fig. 10 would be sufficient to embed in some vascular walls. The interconnecting element of Palmaz are axially aligned insofar as they are attached to each cylindrical element at a axially aligned location.

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GB ^{2.4} Claim ~~23~~ is rejected under 35 U.S.C. § 102(b) as being anticipated by Palmaz ('337).

Palmaz teaches a method of implanting a stent comprising: placing a stent 70 on an expandable portion 88 of catheter 83; delivering the stent to a desired location as seen in fig. 3; expanding the stent as seen in fig. 4; and withdrawing the catheter, leaving the expanded stent. It is noted that the structure of the stent, having only been inferentially recited in the preamble, is not given patentable weight. Applicants have not included the stent in a method step, and thus the specific structure of the stent is not given patentable significance.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 23 is rejected under 35 U.S.C. § 103 as being unpatentable over the prior art admitted by applicants on page 2 of the specification in view of Palmaz ('417) as applied to the claims above.

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Applicants admit to the conventionality of an elongated stent delivery catheters having expandable members at the distal end thereof. The admitted prior art does not teach the specific structure of the stent itself.

To include in a kit the stent as taught by Palmaz with the delivery catheter as taught by the admitted prior art to provide a kit for deploying a stent would have been obvious to one skilled in the art.

Claims 5-7 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112 and to include all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Chris A. Bennett, whose telephone number (703) 308-0980.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

The fax number for this group is (703) 305-3590, 91.

CAB *CAB*
January 23, 1995

Chris A. Bennett
**CHRIS A. BENNETT
PATENT EXAMINER
GROUP 3300**